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JOINT STEERING COMMITTEE ON PUBLIC POLICY
AMERICAN SOCIETY FOR CELL BIOLOGY
AMERICAN SOCIETY FOR BIOCHEMISTRY AND MOLECULAR BIOLOGY
BIOPHYSICAL SOCIETY
GENETICS SOCIETY OF AMERICA

HOW TO MAINTAIN U.S. LEADERSHIP IN BIOMEDICAL RESEARCH

INTRODUCTION

Government investment in biomedical research over the past three decades has catalyzed a scientific revolution. Powerful new methods for studying life forms now offer unprecedented opportunities to understand the fundamental principles of life, to improve human health, and to strengthen the nation's economy through the biotechnology industry, in which the United States remains in the forefront. Further progress and American leadership are, however, threatened by an economic crisis, by the application of political "litmus tests" to science policy, and by the deterioration of the research community's physical and educational resources. We need innovative policies to organize and conduct biomedical research to reap the benefits of recent advances and keep ahead of foreign competitors.

THE PROMISE OF BIOMEDICAL RESEARCH

The traditional goals of biomedical research have been the prevention and treatment of human disease. Unprecedented progress in biology during the past few decades has markedly enhanced the prospects for relief from disease and has inspired a broader view of the possible effects of biomedical research upon our society. The fundamental components of biological systems---cells, genes, and molecules---can now be studied at levels of detail that were unimaginable even ten years ago. Given adequate support, biomedical science now has the tools to discover the basic mechanisms of living systems. This knowledge can transform medicine by allowing rational and less expensive approaches to the diagnosis, treatment and prevention of disease. The growth of the biotechnology industry has proven that new research tools can be rapidly converted to useful products, including novel means to improve human health, and can generate jobs and satellite industries that stimulate economic growth. Biomedical research has the potential to cause wide-ranging effects upon our culture in the following ways.

1) **New approaches to treatment of human diseases.** The prospects for fulfilling the traditional objectives of biomedical research have never been greater, as a result of new-found abilities to understand diseases at a genetic and molecular level. These advances have already stimulated novel approaches to diagnosis, therapy, and drug discovery for cancer and for infectious and inherited diseases.

2) **Progress in preventive medicine.** New biomedical methods offer many opportunities to prevent birth defects, to measure genetically-determined predispositions to disease, to make diagnoses early in the course of an illness, and to produce vaccines against infectious diseases. These approaches can significantly reduce human suffering by preventing or minimizing the effects of serious diseases.

3) **Containment of health-care costs.** It is sometimes claimed that technological advances increase the cost of health-care. But advances in biotechnology can often reduce costs by preventing diseases, diagnosing them at early stages, or providing relatively inexpensive therapies produced in simple biological systems. For example, polio vaccines are much less expensive than iron lungs; a vaccine against hepatitis B, made from recombinant DNA, is less costly than care for chronic hepatitis; and genetically engineered blood cell factors reduce hospitalization for cancer patients undergoing chemotherapy.

4) **Preparation against unanticipated diseases.** The AIDS epidemic, the emergence of Legionnaire's Disease, and the recent resurgence of tuberculosis are grim reminders that we cannot prejudge the spectrum of maladies we will have to confront in the future. For this reason, it is important to support a broadly-based research program that will prepare us to respond to novel diseases. The vigorous funding of research on cancer viruses in the decade preceding the appearance of AIDS fortuitously provided a ten-year head-start towards an understanding of the AIDS virus. In contrast, the neglect of bacteriology, especially the study of mycobacteria, during the past twenty years, has compromised our ability to cope with the current epidemic of tuberculosis.

5) **Economic growth through biotechnology and allied industries.** Advances in basic biomedical research, particularly the development of recombinant DNA methods, stimulated the birth and growth of the biotechnology industry in the United States and its expansion around the world. This industry has prospered in our country because of our solid research base, interactions with a strong pharmaceutical industry, and innovative thinking and financing. Biotechnology has already generated useful and profitable products and promises to produce many more; it offers jobs that have attracted workers with a wide range of technical abilities and educational backgrounds; and it has supported the development of many satellite industries that make the materials required for molecular research here and abroad.

6) **Advances in agriculture.** Feeding the rapidly expanding world population will be a serious problem in the next decades. Genetic engineering, developed in the biomedical sector, has recently been applied to plants. As a result, new agricultural products will have extended shelf lives, resistance to conventional insect and viral infestations, and higher yields. These advances will have profound effects upon food production and distribution in this country and world-wide.

7) **Environmental protection.** Recombinant DNA technology offers multiple strategies for helping our society to cope with environmental problems. For example, genetically altered bacteria can help repair environmental contamination (bioremediation); biomaterials can

replace petroleum-based products and thereby help alleviate the demands for oil; and insect-resistant plants can reduce the use of chemical pesticides.

8) **Public understanding of science and technology.** The excitement and measurable benefits of biomedical research stimulate broad interest in science and technology. A strong national program for biomedical research can have the important secondary effects of encouraging people to seek further education and jobs in biology, improving education in the sciences, and raising the level of scientific literacy in the country.

CHALLENGES TO THE CONTINUED SUCCESS OF BIOMEDICAL RESEARCH IN THE U.S.

Enlightened federal programs for promoting basic research in biology and allied fields over the past few decades have established this country as the world's leader in biomedical research, nurtured the remarkable scientific progress that now promises many improvements in the quality of life, and subsidized the founding of the biotechnology industry with its many economic and social benefits. Nevertheless, American progress and pre-eminence in biomedical research are currently threatened by several factors. If swift and appropriate responses are not made, we will fail to deliver on the promises of biomedical research. Furthermore, our competitors in Japan and the European Community will capitalize on our earlier investments in basic research and attempt to take the lead in biotechnology within the next decade. Thus the biotechnology industry, like the electronics industry, could be transferred overseas, unless we find ways to counteract the problems listed below.

1) **Underfunding of biomedical research.** The productivity of biomedical research is currently limited by available resources. The annual cost of health care is more than $600 billion, but the nation's investment in biomedical research is only about $10 billion. This is low compared to research investments in other areas. (The pharmaceutical industry spends about 10% of its budget on research, the defense industry, about 15%, the health care industry, about 2%.) In the past few years, the growing budget deficit, the recession, competing social priorities, and rising costs of research have conspired to reduce the effective level of federal support for biomedical research, despite the remarkable opportunities for progress. Although funding for the study of some highly visible diseases has been less severely affected, support for many important programs, particularly fundamental research in basic biology, has been inadequate. Budgetary restrictions on biomedical research have caused much promising research to go unfunded and delayed the new discoveries required for practical applications. Such budgetary constraints upon biomedical research not only have an immediate and direct impact on scientific progress, but also discourage students from pursuing science.

2) **Deterioration of the physical infrastructure.** Limited funding for biomedical research has postponed the long-overdue renovation of research facilities and the replacement of outmoded equipment. In many outstanding institutions, the conduct of biomedical research is constrained and even dangerous as a result of crowded, dilapidated laboratories and inadequate instruments. Although in recent years Congress has appropriated substantial funds

for construction at research institutions of their choice, they have done so in a way that circumvents peer review, serves local needs rather than the advancement of science as a whole, slights our academic centers of excellence, and, thus, undermines the cost-effective use of federal funds for research.

3) **Poor administrative organization of science.** The federal bureaucracy has failed to keep pace with developments in science and technology. As a result, agencies that should be working together to promote research in the life sciences are instead isolated in multiple departments with competing agendas. Furthermore, many agencies that fund life sciences research lack appropriate mechanisms for initiating, judging, and administering programs or have not adapted their mechanisms to progress in research. For example, NIH study sections, comprised of scientific peers who review applications, are organized according to outmoded categories. In addition, the scientific community is not adequately involved in administrative decisions to initiate targeted projects.

4) **Inappropriate criteria for selection of scientific leadership.** In recent years, it has become commonplace to consider political views on issues such as abortion and the use of fetal tissue in research in the choice of appointees to high-ranking positions. This tendency has compromised our ability to select federal leaders of American science based on scientific accomplishments and the capacity to manage complex programs and make objective decisions.

5) **Shortsighted objectives for biomedical research.** Constraints on federal support for science have encouraged calls for increased application of current knowledge to practical problems. These appeals have special resonance in biomedical science now that so many opportunities for practical applications are at hand. (For example, the polymerase chain reaction (PCR), a powerful new method for studying genes, based upon the principles of DNA synthesis, has already been used for medical diagnosis, criminal law, evolutionary studies, anthropology, and identification of victims of political oppression.) The improved prospects for direct application of biomedical science to societal problems are important, but they should have their primary effects on the private sector, where such applications are most likely to be developed efficiently. In particular, they should not be used to justify policies that support practical applications at the expense of traditional, broadly conceived explorations of the basic principles of biology through government-supported research in the academic community. If that occurs, we will soon fail to make the new discoveries that are required for continued advances of practical value to society, lose our position of leadership in biomedical research, and discourage the best minds from entering this field.

6) **Obstacles to technology transfer.** Given the requirement to sustain fundamental research, there is also the need to improve the means by which we recognize and develop the application of advances in basic science. Ways must be found to foster technology transfer, preferably in the private sector, because that is where there is the most sensitivity to market forces. The growing federal attention to conflict of interest has sent confused messages to academic scientists and has been a deterrent to technology transfer.

7) **Declining educational programs in science.** Both academic biomedical research and the biotechnology industry depend upon the nation's schools to supply a competent workforce by stimulating interest in scientific thought and by training students in scientific methods. Many indicators show that we are failing to achieve these goals, especially in the early school years and when viewed in comparison to other countries.

RECOMMENDATIONS

1. To Build an Improved National Agenda for Biomedical Research

a) **Develop an investment strategy for biomedical research.** As measured by the percentage of health care costs reinvested in research, biomedical research is underfunded, although it will result in improved health, reduced medical costs, and the creation of jobs in the private sector. It is presently difficult to determine the optimal level of federal biomedical research support and the appropriate allocations to fundamental and applied areas. The government and the scientific community should work together to formulate an economic strategy based on an analysis of the following factors: 1) the opportunities made available by the recent revolution in biology for the prevention and treatment of the major diseases; 2) the potential danger and costs of new epidemics and diseases of modern society; 3) the potential contribution of new treatments to reducing health care costs and improving the quality of life; 4) the potential effects of government sponsored biomedical research on the environment, agriculture and industry; and 5) investment strategies and competition from other countries.

b) **Bring creative science to critical problems.** Biomedical science has contributed effectively to new areas such as AIDS research, biotechnology, rational drug design, cancer research and agriculture. Nevertheless, there are several important problems, such as tuberculosis and sexually-transmitted diseases, that are critical to the national interest and have not received sufficient attention. The best strategy for identifying these problems and for planning to solve them is likely to come from the active participation of the scientific community, rather than from administrative directives. There should be an ongoing planning process, presided over by the NIH Director with members of the intramural and extramural NIH community, to set goals in these areas and to modify NIH policies. Some of the intellectual rigidity within NIH can be traced to the peer review system, which is indispensable but in need of reform. In particular, the system should be periodically reevaluated with the advice of the scientific community so that the organization of the review groups reflect changes in scientific practice.

c) **Develop strategies for improving the application of fundamental discoveries.** The need for expanded research on technology transfer should be met with strategic planning designed to encourage such research in the private sector, by economic incentives, alliances with academia, clarifying the issues of conflict of interest, and other means.

d) **Develop a common strategy for the NIH and the NSF that supports fundamental research.** In the face of well-intentioned calls for more applied research, the President and his

advisor should reiterate their commitment to basic research. New missions of the NIH and NSF in education and in technology should not be allowed to erode the long term investment in fundamental research that has been the source of virtually all the recent advances in biomedical science and biotechnology.

e) **Direct the NIH and NSF to support programs on the basis of scientific rather than political principles.** Narrow political considerations have caused the government to ignore important areas of biomedical concern in reproductive biology, such as research on contraception and population biology. Work on diabetes and Parkinson's disease has been obstructed by preventing scientists from using fetal tissue. The NIH should be given some latitude to direct a limited amount of funds into areas that are deemed important by the intramural and extramural scientific communities for national well being, and the management of the NIH should be insulated from partisan political debates.

2. To Strengthen the Federal Administration of Biological Science

a) **Assure a central role for the President's science and technology advisor.** The President's science and technology advisor should have strong scientific credentials and should play a major role in policy decisions about industrial development, health, environment, and energy, reflecting the importance of science and technology in many aspects of our society. The advisor should coordinate research programs in all relevant government agencies and should be directly involved in proposing legislation, budget planning, and designing scientific programs. Since biology will embrace many of the most significant scientific and technological issues for the 21st century, the advisor should have current knowledge of recent developments in biology and medicine, maintain close contact with active scientists, and have outstanding biomedical scientists among the members of the Office of Science and Technology Planning and the President's Council of Advisors in Science and Technology.

b) **Establish the NIH as an independent federal agency and reconsolidate its authority.** The role of the NIH is too broad to subsume it under the large Department of Health and Human Services. Administratively it has suffered from a chain of command that requires approval from secretaries and undersecretaries with little expertise and interest in science, and it has been damaged by irrelevant political considerations. Its broad role and its nonpolitical nature would be improved by its establishment as an independent agency like the NSF and NASA. All aspects of biomedical research now associated with the NIH should be returned to the full authority of the Director, reversing the autonomy granted to some sectors (such as the National Cancer Institute) by Congressional action.

c) **Employ appropriate criteria for choosing scientific administrators.** Individuals who direct governmental programs in biology and medicine, such as the NIH and the NSF, should be chosen on the basis of their scientific accomplishments, their stature in the research community, and their ability to administer complex scientific organizations. The choices should not be based on political allegiances or on the basis of other irrelevant political considerations.

The tenure of scientific appointments should be tied to professional performance and not to electoral fortunes.

3. To Improve the Practice and Teaching of Science in Academic Institutions

a) Reform the assignment and use of indirect cost money. A more uniform and comprehensible indirect cost policy should be implemented that provides incentives to institutions for cost savings. The policy should insure that funds provided through indirect cost recovery be used only to support the infrastructure necessary for the scientific work. Reforms of the indirect cost policies should be instituted gradually to avoid disrupting academic programs.

b) Develop a program for repairing the scientific infrastructure. The President should propose a program for long term investment in laboratories and equipment. The awards should be based on merit and need and should be peer reviewed. The President should discourage individual set asides and scientifically unsound initiatives.

c) Increase federal attention to science education, particularly in K-12. Science education should become a central issue on the biomedical research agenda, as it directly affects the future of biomedical science in the U.S. and the industrial and scientific base on which it is founded. Since biomedical science is arguably the most exciting area of current science, the one most accessible to the general population, and an area of clear U.S. superiority, biomedical science should play an important role in education of teachers and students.

We believe that these recommendations are realistic goals for a new administration. They will help to control disease, contain healthcare costs, promote technology, stimulate industrial development, advance agriculture, protect the environment, and contribute to the education of the American people.